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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,903	03/01/2004	Gust H. Bardy	1201.1102102	2624

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CROMPTON SEAGER AND TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/790,903	Applicant(s) BARDY ET AL.	
	Examiner Kristen Mullen	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/11/05 (Response).
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-85 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☒ Claim(s) 80-85 is/are allowed.
 6) ☒ Claim(s) 48-79 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 48-50, 52, 54-59, 61-62, 64-67, 69, 71-75 and 77-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (5,385,574).

With respect to claims 48, 55-59, 64-65 and 72-75, Hauser et al. shows a cardioverter-defibrillator (10) comprising a subcutaneous electrically active canister that houses a source of electrical energy, a capacitor, and operational circuitry; a subcutaneous lead or electrode connected to the canister including a subcutaneous cardioversion electrode (28, 29) (Figs. 2, 5, 6) (Col. 2, lines 20-43)

Regarding claims 49-50 and 66-67, Hauser shows the subcutaneous lead further includes one or more sensing electrodes (28, 29, 36) and where the second sensing electrode is electrically insulated from and spaced from the first sensing electrode (Fig. 5).

With respect to claims 52 and 69, Hauser shows a first sensing electrode (36) located adjacent a distal end of the lead, a first cardioversion-defibrillation electrode (28) located proximal to the first sensing electrode and the second sensing electrode (29) located proximal to the first cardioversion-defibrillation electrode (28) (Fig. 6).

With respect to claims 54 and 71, Hauser shows the canister comprises one or more sensing electrodes (80) (Col. 7, lines 16-25).

Regarding claims 61-62, 77 and 78, Hauser shows a second subcutaneous lead (Fig. 6) including a second subcutaneous cardioversion defibrillation electrode (Col. 5, lines 51-59).

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art. The fact that the subcutaneous electrically active canister and subcutaneous electrode are adapted for delivery between the subcutaneous electrically active canister and the subcutaneous cardioversion-defibrillation electrode does not further limit the structure of the ICD. It merely describes how the device is intended to function or how the electrodes are to be placed in the thorax.

Furthermore, the word subcutaneous has been interpreted literally to mean “under the skin”. Thereby, electrodes located within the heart or on the heart are also located under the skin

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 51 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,385,574) as applied to claims 50 and 67. Hauser further shows a first sensing electrode (36) located adjacent a distal end of the lead, a second sensing electrode (28) located proximal to the first sensing electrode (36), a first cardioversion-defibrillation electrode (29) located proximal to the second sensing electrode (28) (Fig. 6). Hauser fails to teach the second sensing electrode is located on the lead about 1 to about 10 cm proximal from the first sensing electrode.

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It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify spacing of the electrodes as taught by Hauser with the specific spacing set forth above, since applicant has not disclosed that this spacing provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any spacing of the electrodes such as the spacing taught by Hauser for a subcutaneous lead used for defibrillating and sensing the heart

5. Claims 53 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,385,574) as applied to claims 50 and 67. Hauser discloses the claimed invention except for second sensing electrode is located on the lead about 1 to about 10 cm proximal from the first sensing electrode and the configuration includes a cardioversion-defibrillation electrode located on a distal end of the lead with a first sensing electrode and second electrode located proximal from the cardioversion-defibrillation electrode. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the electrode arrangement and spacing as taught by Hauser with the specific arrangement and spacing set forth above, since applicant has not disclosed that these arrangement and spacing provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any arrangement and spacing of the electrodes such as the arrangement and spacing taught by Hauser for a subcutaneous lead used for defibrillating and sensing the heart

6. Claims 60 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,385,574) as applied to claims 48 and 64, and further in view of Bennett et al. (5,331,966). Dahl et al. and Anderson et al. are as explained before. Hauser further shows the subcutaneous electrode is provided with one or more sensing electrodes (28, 29, 36) and the canister includes

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one or more sensing electrodes (62, 64, 66, 80) (Fig. 11). Although Hauser fails to show means for selecting two sensing electrodes, attention is directed to Bennett which shows a canister having at least three sensing electrodes (Figs. 2A, 2D, 2E) or the canister having two electrodes on the canister and a third electrode located proximally on a lead (Figs. 2B, 2C) and means for selecting two sensing electrodes. Bennett teaches that the three electrode configuration on the canister (or canister and proximal location on a lead) provides a leadless orientation specific insensitive means for receiving electrical signals from the heart (Abs. Col. 10, lines 52-64).

Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hauser to include the three sensing electrode configuration and selecting means as taught by Bennett in order to provide a leadless orientation specific insensitive means for receiving electrical signals from the heart.

7. Claims 63 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,385,574). Although Hauser fails to show an attachment member located at the distal end of the subcutaneous lead, it is well known in the art to use barbs, tines, corkscrews etc. to fix leads to tissue. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hauser to include an attachment member located at the distal end of the subcutaneous lead, since it well known in the art to do so.

Response to Arguments

8. Applicant's arguments filed 10/11/05 have been fully considered but they are not persuasive.

9. In response to applicant arguments against the 102(b) rejection by Hauser, the examiner asserts that an electrode located within the heart (such as 28 or 29) is also under the skin and thus also fits within the definition of subcutaneous explained above.

10. In response to applicant's arguments against the Hauser and Bennett references individually with respect to claims 60 and 76, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, Hauser does shows sensing electrodes (62, 64, 66, 80) on the canister (Fig. 11). Likewise, Bennett also shows sensing electrodes on a lead (Figs. 2B, 2C).

Terminal Disclaimer

11. The terminal disclaimer filed on 10/11/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 6,721,597 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

12. Claims 80-85 are allowed.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after


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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

kdm